REMARKS

In the Title and Abstract:

The title has been amended to comply with the Examiner's requirement for a new title. The abstract has been amended in response to the Examiner's objection.

In the Specification:

The Examiner objected to the disclosure under MPEP § 608.01 because it contains embedded hyperlinks and/or other forms of browser-executable code. Per the Examiner's request, and in compliance with MPEP § 608.01, Applicant has deleted the embedded hyperlinks and/or other forms of browser-executable code. Therefore, Applicant respectfully requests that this ground of objection be withdrawn.

In the Claims:

Claims 1-24, 29-31, and 37 are cancelled herein without prejudice or disclaimer.

Claims 25-28 are amended to clarify that the recited nucleic acid encodes a polypeptide that inhibits neoplastic growth in tumor cells. No new matter is added by this amendment, which is supported in the specification beginning at page 138, line 13. In addition, the amendments to Claims 25-28 clarify that the claimed nucleic acid sequence encodes a polypeptide without an extracellular domain.

Claim 32 recites only SEQ ID NO: 41, which is noted by the Examiner to be free of the prior art. Claim 32 has been rewritten in independent form. Support for this claim may be found in Figure 17 (SEQ ID NO:41).

Claims 33-34 are amended to depend from Claim 25.

Claim 35 is amended to clarify that the recited nucleic acid hybridizes under high stringency conditions and encodes a polypeptide that inhibits neoplastic growth in tumor

cells. No new matter is added by this amendment, which is supported in the specification at page 30, lines 12-21, and beginning at page 138, line 13. In addition, the amendment to Claim 35 acknowledges that the claimed nucleic acid sequence encodes a polypeptide without an extracellular domain.

Claim 36 is amended to clarify high stringency conditions for hybridization. Support for this amendment may be found at page 30, lines 12-21 of the specification.

Claim 38 is amended to depend from Claim 25. As a result, previously presented Claims 39-41, which directly or indirectly depend from Claim 38, incorporate the limitations of Claim 25.

Claims 42 and 43 are newly added. New claims 42 and 43 do not encompass new matter and are supported at pages 59-62 of the specification.

Oath/Declaration

The oath or declaration was defective because of a non-dated, non-initialed change to the address of inventor Dan L. Eaton. Dan L. Eaton was removed from this application as an inventor pursuant to a 37 CFR § 1.48(b) letter filed on 9 December 2003. Therefore, the oath and declaration currently on file are compliant with 37 CFR § 1.67(a).

Potential Double Patenting:

The Examiner noted that SEQ ID NO: 42 of the instant application is identical to SEQ ID NO: 362 in other filings by Applicant and raised a question regarding double patenting. Pursuant to 37 CFR § 1.105 as cited by the Examiner, Applicant avers to the best of its present knowledge that no claims of the present application conflict with claims presented in applications containing SEQ ID NO: 362.

Claim Rejections:

35 U.S.C. § 102

Claims 22-31 and 33-41 were rejected under 35 U.S.C. § 102(e) as being anticipated by Sheppard et al., U.S. Patent No. 6,197,930. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.01. As amended, all claims of the present application recite – or depend from claims that recite – a functional limitation not found in the Sheppard patent. Specifically, the claimed nucleic acid, whether isolated or in a vector, encodes a polypeptide that inhibits neoplastic growth in tumor cells. The Sheppard reference does not teach this element and therefore does not anticipate the claims currently before the Examiner. Hence, Applicant submits that the grounds for the anticipation rejection have been overcome and request that the Examiner withdraw the § 102 rejection.

Additionally, Applicant thanks the Examiner for expressly noting that Claim 32, which encompasses nucleic acid SEQ ID NO: 41, is neither anticipated nor obvious since "the full-length sequence of SEQ ID NO: 41 is free of the prior art."

35 U.S.C. § 112, second paragraph

Claims 22-41 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states that the recitation of an extracellular domain in these claims is indefinite since the amino acid sequence set forth in SEQ ID NO: 42 is a soluble protein and is not disclosed as being expressed on a cell surface. Claims 22-24, 29-31, and 37 are cancelled in the present paper. Applicant has amended currently pending Claims 25-27 and 35 to clarify that the polypeptide encoded by the claimed nucleic acid does not comprise an extracellular domain. The Examiner's rejection of Claims 28, 32-34, and 38-41 was based on their depending from rejected claims; therefore, the amendments to Claims 25-27 and 35 cure the alleged

indefiniteness of Claims 28, 33-34, and 38-41. Claim 33 has been rewritten in its independent form and therefore this ground of rejection has also been overcome with respect to Claim 33.

The Examiner also rejected Claims 36-37 for indefiniteness because they encompass an isolated nucleic acid that hybridizes under "stringent conditions." The specification's description of hybridization and wash conditions are characterized by the Examiner as "exemplary," not giving sufficient definiteness to these claims. Applicant has amended Claim 36 to reflect that the hybridization of the nucleic acid occurs under high stringency conditions. One example of such high stringency hybridization conditions is set forth at page 30, lines 17-21 of the instant specification. Amended Claim 36 sets forth specific high stringency conditions. The hybridization reaction under the claimed conditions is well-known in the art. Therefore, amended Claim 36 overcomes the stated grounds for rejection and Applicant requests that the rejection be withdrawn.

Accordingly, Applicant submits that it has overcome the rejection for indefiniteness of pending Claims 25-28, 32-36, and 38-41 and requests that the rejection to those claims be withdrawn.

35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 22-26 and 35-41 under 35 U.S.C. § 112, first paragraph, alleging that they fail to satisfy the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

Applicant respectfully disagrees with the Examiner's statement that the written description requirement has not been satisfied. As the Examiner notes, the written description requirement requires that an applicant's specification convey with

reasonable clarity to those skilled in the art, that as of the filing date sought, he or she was in possession of the invention. *Vas-Cath, Inc. v. Mahurkar,* 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). A written description of an invention involving a chemical genus requires a precise definition, such as by structure, formula . . . of the claimed subject matter ***sufficient to distinguish it from other materials***. *Univ. of Calif. v. Eli Lilly & Co.,* 43 USPQ2d 1398, 1405 (Fed. Cir. 1997) (emphasis added). Since one skilled in the art can distinguish a described formula from other formulas and therefore can ***identify many of the species*** that the claims encompass, a described formula is normally an adequate description of the claimed invention. *Id.* at 1406 (emphasis supplied). Moreover, as noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, first paragraph, "Written Description" Requirement ("the Guidelines"), "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." 66(4) *Fed. Reg.* at 1107; 191 USPQ at 97, (emphasis supplied).

Compliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The test is whether the originally filed specification reasonably conveys to a person having ordinary skill in the art that applicant had possession of the subject matter later claimed. *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1991). Moreover, in order to have possession of members of a claimed genus, the specification ***need not*** describe all of the species that the genus encompasses. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991).

In view of the legal standard regarding the written description requirement under 35 U.S.C. § 112, first paragraph, in combination with the interpretation of the written description requirement by the United States Patent and Trademark Office as set forth in the Guidelines, the instant specification satisfies the written description requirement because it

would be clear to one of skill in the art that Applicant possessed the claimed subject matter at the time of filing the instant application.

Specifically, the Examiner rejects Claims 22-26 and 35-41 for lack of written description because the claims do not require that the nucleic acid or encoded polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing features. Further, the Examiner asserts that the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

First, Applicant has cancelled Claims 1-24, 29-31, and 37 without prejudice or disclaimer. Claims 25-26 and 38-41 have been amended to clarify that they are directed to nucleic acid sequences with at least 95% sequence identity to SEQ ID NO: 41 or to a nucleic acid encoding the polypeptide of SEQ ID NO: 42, wherein the nucleic acid encodes a polypeptide that inhibits neoplastic growth in tumor cells. Therefore, the amended claims are not drawn to a genus of nucleic acids defined only by sequence identity, but rather to a genus defined by sequence identity correlated with function.

Further, Applicant discloses structural features of the claimed sequences. For example, Figure 18 discloses several structural features including a signal sequence, N-myristoylation sites, and a cell attachment sequence. Page 102, beginning at line 6, explains a method of making the claimed sequence and page 138, beginning at line 13, describes the function of the claimed sequences, encoding a polypeptide that inhibits neoplastic growth of tumor cells.

The analysis for determining whether the present specification provides written description support for the invention defined by Claims 25-26, 35-36, and 38-41 may be performed by numerous methods, several of which are described in the Guidelines and further exemplified in the Revised Interim Written Description Guidelines Training Materials ("Written Description Training Materials"), published on the USPTO website at http://www.uspto.gov/web/offices/pac/writtendesc.pdf. These Written Description Training Materials are designed to provide additional clarity to the Guidelines which are published in the Federal Register, Volume 66, No. 4, pages 1099-1111. In fact, as

indicated in the USPTO press release of March 1, 2000 introducing the Written Description Examination Training Materials (Press Release #00-15), these training materials were promulgated by the USPTO and are:

> "designed to aid PTO's patent examiners in applying the interim written description and utility guidelines in a uniform and consistent manner to promote the issuance of high quality patents. The training materials will also assist patent applicants in responding to the PTO when utility or written description issues are raised during the examination of a patent application." (emphasis added)

With regard to Claims 25-26, 35-36, and 38-41, the present situation is analogous to Example 14 on pages 53-55 of the Written Description Training Materials. More specifically, in Example 14 on pages 53-55 of the enclosed Written Description Training Materials, a claim directed to a protein and variants thereof having 95% sequence identity, all of which share the same biological function, is analyzed for its compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. The Written Description Training Materials conclude that such a claim satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, when (1) a single protein sequence is actually reduced to practice, (2) procedures for making variants of that "reduced to practice" protein sequence are conventional in the art, and (3) an assay is described which allows identification of other proteins having the same biological activity. The reasoning provided by the USPTO in the Written Description Training Materials is that:

> "[t]here is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO:...does not have substantial variation since all of the variants must possess the specified [biological function] and must have at least 95% identity to the reference sequence, SEQ ID NO:...The single species disclosed ***is representative of the genus*** because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:...which are capable of the specified [biological function]. One of skill in the art would conclude that applicant was in possession of the necessary

> common attributes possessed by members of the genus.....{As such], the disclosure meets the requirements of 35 U.S.C. § 112, first paragraph, as providing adequate written description for the claimed invention." (emphasis added).

Analogous to Example 14 of the Written Description Training Materials, the present specification discloses and actually reduces to practice a nucleic acid recited in Claims 25-26, 35-36, and 38-41 (*i.e.*, SEQ ID NO: 41) as well as a polypeptide encoded by that nucleic acid (*i.e.*, SEQ ID NO: 42). Moreover, the nucleic acid variants encompassed within Claims 25-26 and 38-41 ***do not have substantial variation*** with SEQ ID NO: 41 because (a) they share at least 95% to 99% sequence identity with SEQ ID NO: 41 or the encoded polypeptide (SEQ ID NO: 42) (Applicant notes that methods for routinely determining nucleic acid and/or amino acid sequence identity are described in detail in the present specification at page 23, line 34 to page 29, line 2, *see also* pages 34-54), and (b) they share the biological function of encoding a polypeptide that inhibits neoplastic growth of tumor cells. (Applicant further notes that the specification describes in detail in Example 30 a routine assay that is useful for identifying nucleic acids encoding polypeptides having this biological function). As such, the nucleic acids encompassed within Claims 25-26 and 38-41 all share substantial common structural features (*i.e.*, 95% to 99% sequence identity) and substantial common functional features (*i.e.*, encoding a polypeptide that is able to inhibit neoplastic growth in tumor cells).

Moreover, the present specification also describes conventionally known methods used and known in the art for preparing a multitude of variants (see the present specification at page 59, line 13 to page 63, line 36).

Given the above, currently pending Claims 25-26, 35-36, and 38-41 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph because the specification provides "a precise definition, such as by structure, formula ... of the claimed subject matter *sufficient to distinguish it from other materials*" as required by the Federal Circuit

in *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Moreover, Claims 25-26 are analogous to the claim found to satisfy the written description requirement in Example 14 of the enclosed Written Description Training Materials. As such, under the Guidelines and the examination training materials promulgated by the USPTO for ensuring consistent examination of written description compliance during prosecution of patent applications, the written description requirement of 35 U.S.C. § 112, first paragraph, is satisfied for Claims 25-26, 35-36, and 38-41. Therefore, Applicant respectfully requests this ground of rejection be withdrawn.

CONCLUSION

Currently pending Claims 25-28, 32-36, and 38-41 are patentable. Applicant respectfully requests the Examiner grant early allowance of this application. The Examiner is invited to contact the undersigned attorney for the Applicant via telephone if such communication would expedite this application.

Respectfully submitted,

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